UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

7590 01/11/2005

Stephen Donovan Esq.
2525 Dupont Dr., Mailstop T2-7H
Irvine, CA 92614

EXAMINER	
ROSENTHAL, CASEY S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,816	WONG ET AL.	
	Examin r	Art Unit	
	Casey Rosenthal	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/10/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~2004[illegible]~~. 4-26-04, 8-25-04, 9-10-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statements filed 9/10/2004, 8/25/2004 and 4/26/2004, Power of Attorney filed 6/1/2004, and Preliminary Amendment filed 4/1/2004.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 35 and 52-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of the absence of a release modifier within the original claims or specification; the subject matter is not properly described as filed. Conversely, the instant application teaches the addition of a release modifier in order to alter the rate of release on pages 14-15 of the specification. Furthermore, the claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 35-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (USPN 5,869,079).

7. Wong et al. teaches an implant for treating inflammation of the eye (column 3, lines 65-67) including dexamethasone, a steroidal anti-inflammatory agent, and polylactic acid/polyglycolic acid copolymer (PLGA), a bioerodible copolymer without a release modifier in example 1 of the patent. More specifically, Wong et al. teaches implants particularly for use in the treatment of human (column 1, line 42) ocular conditions, diseases, tumors and disorders (column 6, lines 27-29) including uveitis (column 5, line 7). Wong et al. also teaches various suitable implantable sites including the vitreous cavity (column 6, lines 29-35). Wong et al. teaches other anti-inflammatory steroids including hydrocortisone, cortisone, prednisolone, prednisone, however, dexamethasone is of particular interest (column 3). In addition, Wong et al. teaches the amount of the agent to be within the range of at least about 1 weight percent and usually no more than about 80 weight percent (column 4, lines 16-18) and furthermore exemplifies 50 percent dexamethasone in example 1. The agent weight percent limitations of claims 42-43, 61-63, 73 and 75 of the application fall within the aforementioned range and are therefore satisfied by the teachings of Wong et al. The patent also teaches polyesters specifically, among bioerodible polymers (column 5, line 57). Additionally, Wong et al. also teaches fabricating monolithic implants (column 5, lines 19-24) by means of extrusion (example 1) into various shapes including particles, sheets, patches, plaques, fibers, and microcapsules (column 5, lines 16-18). Lastly,

Wong et al. also discloses that an implant can be formulated to release an active agent over a period of at least about 3 days, usually at least about 1 week, and not more than about 1 year, usually not more than about 3 months (column 4, lines 59-63). Wong et al. also discloses specifically a time frame of about 4 to 6 weeks for the treatment of uveitis (column 5, lines 7-8). Wong et al. also discloses that the size and form of the implant can be used to control the rate of release, period of treatment, and drug concentration (column 7, lines 52-54).

8. Wong et al. does not teach the exact formulations and rates of release described in claims 35, 39-41, 52-53, 57-60, 62-73, 75-77 of the application, however it would have been obvious to someone skilled in the art through routine experimentation to optimize formulations by changing the size and form of the implant as suggested by Wong et al. A person of ordinary skill in the art would have been motivated to make such modifications because different ocular conditions call for different medicaments. The expected result would be several formulations of implants, each formulation made for a specific ocular inflammation-mediated condition.

9. Claims 48-50 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. in view of Guo et al. (USPN 6,217,895 B1).

10. Wong et al. discloses the elements discussed above in paragraphs 3-8 of the rejection. However, Wong et al. does not specifically disclose proliferative

vitreoretinopathy (VPR), macular edema, or flucinolone acetonide. Guo et al. discloses an ocular implant capable of delivering corticosteroids including dexamethasone and flucinolone that can treat various conditions including uveitis, macular edema, and PVR (column 2; examples 1-2). It would have been obvious to someone skilled in the art to use another corticosteroid such as flucinolone acetonide to treat other ocular inflammatory conditions such as macular edema and PVR as suggested by Guo et al. The expected result would be particular implants capable of treating patients with a specific inflammatory ocular condition.

Conclusion

11. All claims have been rejected, no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Rosenthal whose telephone number is 571-212-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Rosenthal
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600